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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

HUNNICUTT, RACHEL KAPUST

ART UNIT PAPER NUMBER

1647

DATE MAILED: 02/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/063,570

Applicant(s)

EATON ET AL

Examiner

Rachel K. Hunnicutt

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application:
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 0902.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see, for example, p. 31 and 35). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The use of the trademarks SEPHADEX™ (p. 86), SEPHAROSE™ (p. 86), TWEEN™ (p. 96), PLURONICS™ (p. 96), MATCHMAKER™ (p. 97), LUPRON DEPOT™ (p. 111), LIFESEQ™ (p. 113), SUPERSRIPT™ (p. 114), KLENTAQ™ (p. 117), QIAQUICK™ (p. 119), POROS™ (p. 126), SUPERFECT™ (p. 129), FUGENET™ (p. 129), and BACULOGOLD™ (p. 131) have been noted in this application. They should be capitalized (in all capital letters) wherever they appear and be accompanied by the generic terminology. Applicants should check the rest of the specification for other trademarks and for other references to the above-cited trademarks.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 4, and 6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1, 4, and 6 are drawn to antibodies that bind to the polypeptide comprising SEQ ID NO: 64, all of which are unaltered, naturally occurring articles. Thus, they are not articles of "manufacture". These rejections may be obviated by

Art Unit: 1647

amending the claims to read “an isolated antibody” or “a purified antibody” so long as there is support for the amendments in the specification.

Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. Claims 1-6 are directed to antibodies that bind to polypeptides comprising SEQ ID NO: 64. The claimed antibodies are not supported by either a specific and substantial asserted utility or a well-established utility.

A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a “real world” use for the claimed invention. See *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966):

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

The antibodies of the current invention bind to polypeptides comprising SEQ ID NO: 64. However, there is no utility for a polypeptide comprising SEQ ID NO: 64. Uses such as assaying for binding partners (p. 95), using polypeptides as molecular weight markers (p. 92), and screening for agonists and antagonists of PRO3566 (p. 95-99) are useful only in research to determine the function of the encoded protein itself. There is no “specific benefit in currently available form” to be derived from such studies. Applicants also teach that the PRO3566 polypeptide or agonists or antagonists of PRO3566 may be used in the preparation of medicaments or in gene therapy (Examples 12 and 13). Even though Applicants teach that PRO3566 DNA is “more highly expressed” in normal skin cells and esophageal tumor cells when compared to melanoma tumor cells and normal esophageal cells, respectively (p. 142), there is no guidance in the specification as to how high levels are. The asserted utility in diagnosis and treatment of the aforementioned cancers is not substantial. It is not clear whether the overexpression of PRO3566 is statistically significant and whether such overexpression is correlated to the overexpression of the encoded protein or whether it is due to aneuploidy. The

Art Unit: 1647

specification fails to disclose the biological significance of this overexpression. The specification also does not teach whether the overexpression is the cause or the result of the tumors. The only thing Applicants teach is that the gene was “more highly expressed”, and this does not enable the skilled artisan to differentiate amongst expression levels in order to diagnose any diseases. Clearly further research and experimentation would be required to find out whether PRO3566 is useful as asserted. See *Brenner v. Manson*, noting that “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.” A patent is therefore not a license to experiment. Further research would be required to determine how and if PRO3566 is involved in any disease.

The invention also lacks a well-established utility. A well-established utility is a specific, substantial, and credible utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material. The specification fails to assert any activity for the polypeptide. Applicants have not asserted that PRO3566 is a member of any protein family nor have Applicants asserted that PRO3566 is homologous to any known proteins. Thus, PRO3566 lacks a well-established utility.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Art Unit: 1647

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-5 are drawn to antibodies which bind to a polypeptide comprising SEQ ID NO: 64. Claim 6 is drawn to an antibody that specifically binds to a polypeptide having the amino acid sequence of SEQ ID NO: 64 (PRO3566). It is not clear from either the claims or the specification what the difference is between an antibody that binds and an antibody that specifically binds. One skilled in the art would not be reasonably apprised of the scope of the invention. It is unclear what amount of binding would be considered to be "specific" such that an antibody that specifically binds a polypeptide comprising SEQ ID NO: 64 would be distinguishable from an antibody that binds a polypeptide comprising SEQ ID NO: 64.

Conclusion

NO CLAIMS ARE ALLOWED.

The following articles, patents, and published patent applications were found by the Examiner during the art search while not relied upon are considered pertinent to the instant application:

NCBI Accession No. BAA88132, December 8, 1999, Oka *et al.*

NCBI Accession No. AC006163, December 8, 1998, Janer *et al.*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel K. Hunnicutt whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1647

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RKH

1/6/05


JANET ANDRES
PRIMARY EXAMINER